



APR 3 2006

3/28/2006

Office of Nutritional Products, Labeling and Dietary Supplements
(HFS-820)

Center for Food Safety and Nutrition

Food and Drug Administration

5100 Paint Branch Parkway

College Park, MD 20740-3835

Re: New Dietary Ingredient Notification (NDI) for omega-3 phytosterol esters

Dear Sir/Madame:

In accordance with the Dietary Supplement Health and Education Act of 1994 (DSHEA), 21 U.S.C. §350b (a) (2), and with final regulations published in the Federal Register (1997, 62:49886-49892, 21 C.F.R. § 190.6) "Requirement for Premarket Notification", Enzymotec, Ltd. is hereby notifying the FDA of its intent to market the CardiaBeat™ dietary supplement product containing the new dietary ingredient, omega-3 phytosterol esters. Enzymotec had previously filed an NDI for CardiaBeat on January 17, 2005. FDA responded on May 21, 2005 with questions regarding whether CardiaBeat met the statutory definition of a "dietary ingredient" under U.S.C. 321(ff)(1) and whether there was an adequate basis to reasonably support its safety in use. The recommended use of CardiaBeat is the consumption of two capsules or 2.0 g/day, in the form of a 1 g capsule twice per day with meals. This recommended usage would provide an intake of not less than 700 -800 mg phytosterols (as free phytosterols) and 650 mg of DHA and EPA.

In this submission, we have defined the new dietary ingredient as omega-3 phytosterol esters which are blended with DHA/EPA enriched fish oil containing fatty acid diglycerides and triglycerides to formulate the CardiaBeat product. DHA/EPA enriched fish oil is added and blended with the omega-3 phytosterol

ester solution so as to achieve the CardiaBeat product's specifications for total phytosterols and DHA/EPA content.

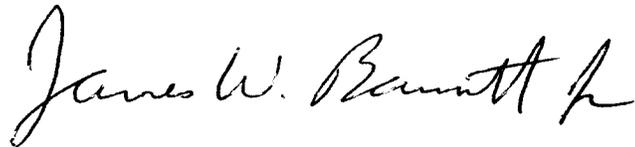
This submission presents significant research and a biological mechanism which demonstrates that omega-3 phytosterol esters are present in virtually all marine foods consumed in the human diet, and as such, meet the statutory definition of a new dietary ingredient by supplementing their natural presence in the diet.

In order to address FDA's questions regarding comparability and safety of the product, we present comparisons of the phytosterol and fatty acid composition of the Enzymotec product to other similar phytosterol and omega-3 fatty acid containing products approved as GRAS by FDA. As discussed in our safety evaluation, the omega-3 phytosterol esters and other ester compounds are rapidly degraded in the gut by enzymatic activity and hydrolysis, which is followed by absorption in the enterocytes for endogenous reesterification. This results in consumers' exposure to essentially the same plant phytosterol and omega-3 fatty acid ingredients that have received broad scientific acceptance as beneficial components of foods and as dietary supplements with increasingly proven health benefits. Therefore, we believe that the safety of the CardiaBeat product is well established by history of use and studies on these similar materials, as well as the studies conducted by Enzymotec.

Based on the information in the attached NDI submission, we believe that FDA should accept this filing on behalf of Enzymotec, Ltd. as providing sufficient evidence that the CardiaBeat™ dietary supplement product, containing the new dietary ingredient, omega-3 phytosterol esters, meets the statutory definition of a new dietary ingredient and can reasonably be expected to be safe for human consumption at the intended use levels proposed.

Should you have any questions regarding this notification, feel free to call me at 512-266-2620 or e-mail to jbarnett@aacgroup.com. We will respond promptly to any questions you might have.

Best regards,

A handwritten signature in cursive script that reads "James W. Barnett Jr".

James W. Barnett, Jr., Ph.D., DABT

Authorized Agent for Enzymotec for NDI Notification